

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of: Michael Didriksen, et al.

Application No.: 10/568,133

Confirmation Number: N/A

Filed: February 10, 2006

Art Unit: N/A

For: THE COMBINATION OF A SEROTONIN
REUPTAKE INHIBITOR AND A GLYCINE
TRANSPORTER TYPE 1 INHIBITOR FOR
THE TREATMENT OF DEPRESSION

Examiner: Not Yet Assigned

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement is submitted in accordance with 37 C.F.R. 1.97, 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

1. This IDS should be considered, in accordance with 37 C.F.R. 1.97, as it is filed: (Check one of the boxes A-D)

- ☒ A. Within three months of the filing date of the above-identified national application or within three months of the entry into the national stage of the above-identified international application.
- ☐ B. before the mailing date of a first office action on the merits, or a first office action after filing a request for continued examination.
- ☐ C. after (A) and (B) above, but before final rejection or allowance, and Applicants have made the necessary statement in box "i" below or paid the necessary fee in box "ii" below.

(check one of the boxes "i" and "ii" below:)

- ☐ i. Counsel states that, upon information and belief, each item of information listed herein was
(check one of boxes (a) or (b))
 - ☐ (a) first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS; or
 - ☐ (b) was not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of undersigned after making reasonable inquiry, was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.
- ☐ ii. A check for the fee set forth in 1. 17(p), presently believed to be \$180, is enclosed.
- ☐ D. after (A), (B) and (C) above, but before payment of the issue fee: Applicant petitions under 37 C.F.R. 1.97(d) for the consideration of this IDS. Under 37 CFR 1.17(i) a check in the amount of \$180.00 is enclosed. Counsel certifies that, upon information and belief, each item of information listed herein was
(check one of boxes (a) or (b))
 - ☐ (a) first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS; or
 - ☐ (b) was not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of undersigned after making reasonable inquiry, was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.

2. In accordance with 37 C.F.R. 1.98, this IDS includes a list (e.g., form PTO/SB/08) of all patents, publications, or other information submitted for consideration by the office, either incorporated into this IDS or as an attachment hereto. A copy of each document listed is attached, except as explained below.

(check boxes A, B and/or C and fill in blanks, if appropriate.)

- ☐ A. Pursuant to the Notice issued by the United States Patent and Trademark Office dated July 11, 2003 waiving the requirements of 37 C.F.R. § 1.98(a)(2)(i), a copy/copies of the United States Patent on PTO/SB08 is/are not being submitted.
- ☐ B. Document(s) _____ is (are) deemed substantially cumulative to document(s) _____, and, in accordance with 1.98(c), only a copy of each of the latter documents is enclosed.

- ☐ C. Certain documents were previously cited by or submitted to the Office in the following prior applications, which are relied upon under 35 U.S.C. 120:

[SERIAL NO. & FILING DATE].

Applicant identifies these documents by attaching hereto copies of the forms PTO-892, PTO-1449 and/or PTO/SB/08 from the files of the prior application(s) or a fresh PTO/SB/08 listing these documents, and request that they be considered and made of record in accordance with 1.98(d). Per 37 CFR 1.98(d), copies of these documents need not be filed in this application.

☐ 3. Cite No. BC is not in the English language. In accordance with 1.98(c), Applicant states:

- ☒ An English translation of each document (or of the pertinent portions thereof), or a copy of each corresponding English-language patent or application, or English-language abstract (or claim) is enclosed.
- ☐ The requirement for a concise explanation of the relevance of any foreign language document is satisfied by the attached search report; citation of the documents cited in the search report shall not be construed as an admission that they are or are considered to be, material to patentability of the subject matter claimed herein (See MPEP §609).
- ☐ A concise explanation of the relevance of document(s) _____ is set forth as follows: [Insert concise explanation of relevance]
- ☐ A concise explanation of the relevance of document(s) _____ can be found on page(s) _____ of the specification.
- ☐ A concise explanation of document(s) _____ can be found on the attached sheet.

☐ 4. No explanation of relevance is necessary for documents in the English language (see reply to Comments 67 in the preamble to the final rules; 1135 OG 13 at 20).

☐ 5. Other information being provided for the examiner's consideration follows:

[A/An _____ Search Report, dated _____, which issued during the prosecution of _____ Application No. _____ which corresponds to the present application.]

6. In accordance with 37 C.F.R. 1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search has been made or that information cited is,

or is considered to be, material to patentability as defined in §1.56 (b), or that any cited document listed or attached is (or constitutes) prior art. Unless other-wise indicated, the date of publication indicated for an item is taken from the face of the item and Applicant reserves the right to prove that the date of publication is in fact different.

CROSS REFERENCE UNDER 37 C.F.R. §1.78 TO RELATED APPLICATIONS

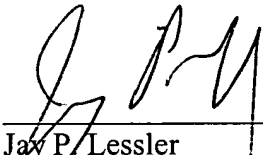
Pursuant to 37 C.F.R. (§1.78, Applicant notes that the above-identified patent application may be related to the following U.S. Patent Applications:

(1) U.S. Provisional Application Serial No _____, filed _____.

Early and favorable consideration is earnestly solicited.

Respectfully submitted,

May 8, 2006



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Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/568,133
				Filing Date	February 10, 2006
				First Named Inventor	Michael Didriksen
				Art Unit	N/A
				Examiner Name	Not Yet Assigned
Sheet	1	of	2	Attorney Docket Number	05432/100N212-US1

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
	BA	EP 0687 472 A2	12-20-1995	Eli Lilly and Company		
	BB	EP0 714 663 A2	06-05-1996	Eli Lilly and Company		
	BC	WO 97/28141	08-07-1997	Pierre Fabre Medicament		
	BD	WO 96/03400	02-08-1996	PFIZER INC.		
	BE	EP-A-701819	08-16-2000	PFIZER INC.		
	BF	WO 99/13877	03-25-1999	ASTRA AKTIEBOLAG		

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	CA	Trends in Pharmacological Sciences, - 5HT _{1A} receptor antagonists in combination therapy - 5-HT and antidepressants: new views from microdialysis studies- TIPS - July 1993 (Vol. 14) - 2 pages.	
	CB	Pierre Blier, M.D. et al. - Journal of Clinical Psychopharmacology; Copyright 1987; Modifications of the Serotonin System by Antidepressant Treatments: Implications for the Therapeutic Response in Major Depression - pages 24S-35S.	
	CC	Roberto Invernizzi et al. - Citalopram's ability to increase the extracellular concentrations of serotonin in the dorsal raphe prevents the drug's effect in the frontal cortex - Brain Search, 584 (1992); pages 322-324.	
	CD	Stephan Hjorth - Serotonin 5 HT _{1A} Autoreceptor Blockade Potentiates the Ability of the 5-HT Reuptake Inhibitor Citalopram to Increase Nerve Terminal Output of 5-HT In Vivo: A Microdialysis Study; Journal of Neurochemistry; 1993 International Society of Neurochemistry.	
	CE	Robert B. Innis et al.; Pertussis toxin blocks 5-HT _{1A} and GABA _B receptor-mediated inhibition of serotonergic neurons; European Journal of Pharmacology, 143 (1987); pages 195-204.	
	CF	S.E. Gartside et al.; Interaction between a selective 5HT _{1A} receptor antagonist and an SSRI in vivo: effects on 5-HT cell firing and extracellular 5-HT; British Journal of Pharmacology (1995) 115, 1064-1070.	
	CG	Pierre Blier et al. - Current advances and trends in the treatment of depression - 1994, Elsevier Science Ltd.; TIPS - July 1994 (Vol. 15), pages 220-226.	
	CH	Wojciech Danyasz et al. Glycine and N-Methyl-D-Aspartate Receptors: Physiological Significance and Possible Therapeutic Applications; Pharmacological Reviews; Copyright 1998 by The American Society for Pharmacology and Experimental Therapeutics; Vol. 50 No.	

Examiner Signature		Date Considered	
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Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/568,133
				Filing Date	February 10, 2006
				First Named Inventor	Michael Didriksen
				Art Unit	N/A
				Examiner Name	Not Yet Assigned
				Attorney Docket Number	05432/100N212-US1
Sheet	2	of	2		

		4; pages 598-664.	
	CI	Gabriel Nowak et al. - Strychnine-insensitive Glycine/NMDA Sites Are Altered In Two Stress Models of Depression; Polish Journal Of Pharmacology Pl. J. Pharmacol, 1998, 50, pages 365-369.	
	CJ	Mariusz Papp et al.- Antidepressant-like effects of 1-aminocyclopropanecarboxylic acid and D-cycloserine in an animal model of depression; European Journal of Pharmacology 315 (1996) 145-151.	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	
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